

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,888	03/23/2007	Barry James White	4033. 3004 US 8755	
	7590 11/29/200 ENT LAW GROUP, P	EXAMINER ·		
209 MAIN STF	REET	HEINCER, LIAM J		
N. CHELMSFORD, MA 01863			ART UNIT	PAPER NUMBER
			1796	
·			MAIL DATE	DELIVERY MODE
			11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/583,888	WHITE ET AL.				
Office Action Summary	Examiner	Art Unit				
	Liam J. Heincer	1796				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. lely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 27 M	<u>arch 2007</u> .					
2a) This action is FINAL . 2b) ⊠ This	This action is FINAL . 2b)⊠ This action is non-final.					
3) Since this application is in condition for allowar	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1-10 and 14 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-10 and 14</u> is/are rejected.						
7) Claim(s) <u>6,8 and 9</u> is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)☐ Some * c)☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
oce the attached detailed office action for a list	or the certified copies not receive					
Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date.						
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>5/2007</u> . 5) Notice of Informal Patent Application 6) Other:						

Art Unit: 1796

DETAILED ACTION

Claim Objections

Claim 3 is objected to because of the following informalities: Claim 3 contains capital letters. Capital letters are reserved for the beginning of claims and for proper names. See MPEP § 608.01(j). Appropriate correction is required.

Claim 6 is objected to because of the following informalities: there is a typo in claim 6 such that it reads "one or other" rather than "one of the other". Appropriate correction is required.

Claims 8 and 9 are objected to because of the following informalities: the instant claims are method claims but they depend from claim 6, a claim directed towards a composition. Appropriate correction is required. For the purpose of further examination the claims are interpreted as depending form claim 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Considering Claim 4: Claim 4 recites the limitation "the partially N-acetylated chitosan" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Application/Control Number: 10/583,888

Art Unit: 1796

Claims 1, 2, 5, 6, 10, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Langer et al. (US Pat. 6,224,893).

Considering Claims 1, 2, and 5: Langer et al. teaches a semi interpenetrating network (3:10-15) which comprises a crosslinked chitosan (6:45-50) and anionic hyaluronic acid (4:50-5:2). Langer et al. teaches a mixture of ionically crosslinkable compounds/hyaluronic acid and a covalently crosslinkable compounds/chitosan that forms a semi interpenetrating network (10:8-20). This would be done by selectively adding covalent cross-linking agents (6:46-54).

Considering Claim 6: Langer et al. teaches the network as additionally comprising other components of the extra cellular matrix (4:1-8).

Considering Claim 10: Langer et al. teaches the composition as being a biomaterial (2:19-24).

Considering Claim 14: Langer et al. teaches the composition as being a hydrogel (2:39-42).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Application/Control Number: 10/583,888

Art Unit: 1796

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al. (US Pat. 6,224,893) as applied to claim 1 above, and further in view of Hudson et al., Chitin and Chitosan.

Considering Claims 3 and 4: Langer et al. teaches the composition of claim 1 as shown above.

Langer et al. does not teach using a chitosan from the claimed group. However, Hudson et al. teaches using a partially N-acetylated chitosan with a degree of acetylatinon of from 45 to 55% (pg. 2, ¶3) in a cross-linked chitosan gel (pg. 8, ¶4). Langer et al. and Hudson et al. are combinable as they are concerned with the same field of endeavor, namely chitosan hydrogels. I would have been obvious to a person having ordinary skill in the art at the time of the invention to have used the partially acetylated chitosan of Hudson et al. in the composition of Langer et al., and the motivation to do so would have been, as Hudson et al. suggests, this chitosan is soluble at neutral conditions, removing the need for a neutralization step (pg. 5, ¶2).

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langer et al. (US Pat. 6,224,893) in view of Hudson et al., Chitin and Chitosan.

Considering Claims 7-9: Langer et al. teaches a method of making semi interpenetrating network (3:10-15) which comprises a crosslinked chitosan (6:45-50) and anionic hyaluronic acid (4:50-5:2). Langer et al. teaches a mixture of ionically crosslinkable compounds/hyaluronic acid and a covalently crosslinkable compounds/chitosan that forms a semi interpenetrating network (10:8-20). This would be done by selectively adding covalent cross-linking agents (6:46-54).

Langer et al. does not teach the reaction conditions being as claimed. However, it is well known in the art to optimize result effective variables such as pH. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have used a pH of around 7 in the method of Langer et al., and the motivation to do so

Application/Control Number: 10/583,888 Page 5

Art Unit: 1796

would have been there would be no need for a neutralization step in the process. See MPEP §2145.05.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO Form 892.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJH

MARK EASHOO, PH.D. SUPERVISORY PATENT EXAMINER

November 1, 2007

11/26/07